



Standard Operating Procedure

**SUBJECT: Application's Standard Library
Maintenance under the caBIG™
Program**

SOP No.: CR-005

Version No.: 2.0

Effective Date: 12/11/2006

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Standard Operating Procedure – Application's Standard Library Maintenance under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

Issued Date: October 30, 2006

Effective Date: December 11, 2006

Department Approval:

Peter Covitz

Chief Operating Officer, NCICB

QA Approval:

George Komatsoulis

Director of Quality Assurance

Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.



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Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/2005	SOP Working Group	N/A	Initial release.
2.0	10/30/2006	BP SIG/SOP WG	All pages	Annual update.



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1. Purpose

This SOP describes the process by which the application's Standard Library for a clinical data management application is managed to support clinical research trials conducted under the caBIG™ Program. The objective is to ensure that the application's standard library is managed appropriately, to enable standards and sustain data interoperability.

2. Scope

This SOP applies to the maintenance of the application's standard library for the clinical data management applications in support of clinical research trials under the caBIG™ Program at the National Institute of Cancer (NCI).

3. Requirements

- 3.1 Common Data Elements (CDEs), that electronically represent the paper case report form (CRF), enable the electronic collection of clinical trial data are to be stored and managed in the application's standard library.
- 3.2 The application's Standards Librarian manages the CDEs used by Study Designers to create clinical research trials in a clinical data management application. These activities include: activate CDEs for use in production, retire CDEs that are no longer used or have been updated or modified, and work with the caDSR Curator when new CDEs are required to support clinical trials.
- 3.3 The *SOP for CDE Curation* should be followed when new elements need to be created and added to the application's standard library.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	N/A	SOP WG Glossary of Terms
4.3	N/A	ICH E9
4.4	N/A	ICH E6 Good Clinical Practice
4.5	CR-004	SOP for CDE Curation
4.6	CR-001	SOP for Study Setup



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5. Roles & Responsibilities

Role	Responsibility
Study Designer	<ul style="list-style-type: none">• Work with the Study Coordinator and the application's Standards Librarian to select appropriate CDEs to support protocol data requirements.
Study Coordinator/Clinical Data Manager	<ul style="list-style-type: none">• Work with the Study Designer and the application's Standards Librarian to review and select CDEs in support of protocol requirements.
Application's Standards Librarian	<ul style="list-style-type: none">• Work with the Study Design, the Study Coordinator to select CDEs that support protocol data collection requirements.• Manage all CDEs and other metadata objects within the clinical data management application to support the planning, set-up, and execution of the clinical research trial (e.g., activates for production, retires objects).• Manage the process of loading and activating new CDEs.

6. Attachments

This SOP will be used in conjunction with the following attachments. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Application's Standard Library Maintenance	This document provides instructions for the management of CDEs and other metadata objects within the application's Standards Library. It provides guidance to assure that the application's standards library is managed in a consistent manner.
2) Process Flow for Application's Standard Library	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Managing and Maintaining the Application's Standard Library Process Flow